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| APPLICATION NO.                                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|---------------------------------------------------------------------|-------------|----------------------|--------------------------------|------------------|
| 10/039,307                                                          | 10/26/2001  | Michael R.S. Hill    | P-8969.00                      | 2140             |
| 27581                                                               | 7590        | 08/21/2006           |                                |                  |
| MEDTRONIC, INC.<br>710 MEDTRONIC PARK<br>MINNEAPOLIS, MN 55432-9924 |             |                      | EXAMINER<br>OROPEZA, FRANCES P |                  |
|                                                                     |             |                      | ART UNIT<br>3766               | PAPER NUMBER     |

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|------------------------------|------------------------|---------------------|--|
|                              | 10/039,307             | HILL ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Frances P. Oropeza     | 3766                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

## Disposition of Claims

4)  Claim(s) 1-40 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-40 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/27/06.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

**DETAILED ACTION**

***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 6/12/06 has been entered.
  
2. The Applicant amended at least the independent claims in the response file 12/7/05, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 112***

3. Claims 29-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner is unable to find the limitation in quotations in the specification:

- claim 29 – “improving the neuro-endocrinological system” (lines 1 and 3) and “balance neuro-endocrinological system” (lines 7-8),
- claim 30 – “improve imbalance of an neuro-endocrinological system” (lines 7-8),
- claim 31 – “improving imbalance of the endocrinological system” (lines 1-3),

- claim 32 – “improving imbalance of the neuro-endocrinological system” (lines 1-3) and “alter the neuro-endocrinological system” (lines 9-10),
- claim 33 – “treating imbalance of the endocrinological system ” (lines 1-2).

New matter may not be added at this point in the process. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. Claims 1, 2, 4-13, 15-18, 20-34 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) and Collins (US 5203326) in view of Sweeney et al. (US 6400982).

Obel et al. disclose an implantable electrical nerve stimulator/ pacemaker for a human/ mammal, the nerves being automatically stimulated in the region of the thoracic vertebra T2 providing electrical communication and the stimulation coordinated with the heart to provide resynchronization therapy (abstract; col. 1 @ 15-24; col. 3 @ 8-28 & 42-45; col. 3 @ 62 – col. 4 @ 26; col. 5 @ 25-64). Anti-tachycardia pacing may be incorporated (col. 9 @ 53 – col. 10 @ 2). Cardiac disease associated with the loss of vagal tone is treated automatically using neural stimulation (col. 1 @ 9-13; col. 5 @ 3-18). Obel et al. teach the inclusion of tachycardia pacing therapies to treat arrhythmias that accompany the lost of vagal tone and arrhythmias that are not treated by vagal stimulation alone (col. 5 @ 3-16; col. 6 @ 66 – col. 7 @ 4; col. 9 @ 53 - col. 10 @ 2).

As to the statement: Ventricular dysfunction, heart failure, imbalance of the autonomic tone, imbalance of the endocrinological system and imbalance of the neuro-endocrinological system are recognized to be disease conditions that are often cluster together in that they have common elements and lead to compromised cardiac systems:

Obel et al. teach:

- vagal nerve stimulation treats heart failure (col. 1 @ 9-19),
- vagal nervous system stimulation ameliorates myocardial ischemia and maintains adequate heart rate (col. 3 @ 13-19),
- the cardio-inhibitory center of the nervous system exerts vagal tone on the heart (col. 5 @ 3-9), and
- selective electrical stimulation of the right or left vagus nerve brings ventricular tachycardia into control (col. 5 @ 12-16).

It is well known in the art as disclosed in US 5203326 to Collins (cited as art made of record) that:

- electrical stimulation of the nerves of the autonomic nervous system can be used to the control the heart (abstract),
- the autonomic nervous system includes the sympathetic and the parasympathetic nervous systems that regulate activities of the cardiac muscle (heart) and the glands (endocrine system) (col. 1 @ 36-39), and
- the autonomic nervous system can be stimulated by the vagal nerve to treat arrhythmias.

Hence as to the statement above and based on the teachings of Obel et al. and Collins:

- Ventricular dysfunction --- (ventricular tachycardia – Obel et al (col. 5 @ 12-16)),
- heart failure --- (Obel et al. (col. 1 @ 9-19)),
- imbalance of the autonomic tone --- (imbalance in the systems of the autonomic nervous system, the sympathetic and parasympathetic nervous systems, the imbalance producing arrhythmias – Collins (col. 5 @ 5-40; col. 5 @ 59 – col. 6 @ 35)),
- imbalance of the endocrinological system --- (imbalance in the sympathetic and parasympathetic nervous systems that regulate the glands (endocrine system) – Collins (col. 1 @ 36-39; col. 5 @ 5-40; col. 5 @ 59 – col. 6 @ 35)),
- and imbalance of the neuro-endocrinological system --- (imbalance in the sympathetic and parasympathetic nervous systems (the “neuro”), the sympathetic and parasympathetic nervous systems regulating the glands (endocrine system), (the “endocrinological”) – Collins (col. 1 @ 36-39; col. 5 @ 5-40; col. 5 @ 59 – col. 6 @ 35)),

are recognized to be disease conditions that are often cluster together in that they have common elements and lead to compromised cardiac systems (citation above from Obel et al. and Collins).

As discussed in the previous five paragraphs of this action, modified Obel et al. disclose the claimed invention except for delivering overdrive pacing.

Sweeney et al. ('982) teach arrhythmia prediction and treatment using vagus nerve stimulation and overdrive pacing for the purpose of preventing or minimizing the consequences of the arrhythmia. It would have been obvious to one having ordinary skill in the art at the time

of the invention to have used overdrive pacing in the modified Obel et al. system in order to provide short-term and immediate therapies known to prevent the occurrence of the arrhythmia (abstract; col. 5 @ 6-17; col. 8 @ 63-67; col. 22 @ 16-52).

5. Claims 3, 19, and 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) and Collins (US 5203326) in view of Sweeney et al. (US 6400982) and further in view of Adams (US 57992187).

As discussed in paragraph 4 of this action, modified Obel et al. disclose the claimed invention except for the driver circuit delivering high-voltage stimulation (claim 39), and the electrode located external to the patient's body (claims 3 and 19).

As to delivering high voltage stimulation, Adams teaches cardiac arrhythmia treatment using cardioversion/ defibrillation shock therapy for the purpose of converting dysrhythmia to normal sinus rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used high voltage stimulation in the modified Obel et al. system in order to offer a proven alternate treatment for arrhythmias so the dysrhythmia is effectively treated before the patient suffers any ill effects from the dysrhythmia (col. 3 @ 1-8).

As to the electrode being located external to the patient's body, Adams teaches pain suppression treatment using an electrode (100) located external to the patient's body at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient's body in the modified Obel et al. system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient's pain, apprehension and anxiety is controlled (abstract;

col. 2 @ 48-55; col. 3 @ 1-8 & 45-48; col. 7 @ 11-24). It is noted both electrical and electromagnetic pain suppression systems are well known in the art, and absent any teaching of criticality or unexpected results merely changing the type of system from an electromagnetic system to an electrical system would be an obvious design choice.

6. Claims 14, 35 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) and Collins (US 5203326) in view of Sweeney et al. (US 6400982) and further in view of Sweeney et al. (US 6272377).

As discussed in paragraph 4 of this action, modified Obel et al. disclose the claimed invention except for the electrode being located on an intrinsic cardiac ganglia (claims 14, 35) and providing a drug delivery device with agent (claim 40).

Sweeney et al. ('377) teach arrhythmia treatment using drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) for the purpose of preventing the development of an arrhythmia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) in the modified Obel et al. system in order to provide alternate proven means to prevent or reduce the consequences of the arrhythmia (abstract; col. 4 @ 61 – col. 5 @ 5; col. 8 @ 49-55).

*Specification*

7. The amendment filed 12/7/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows as indicated by the quotations:

- claim 29 – “improving the neuro-endocrinological system” (lines 1 and 3) and “balance neuro-endocrinological system” (lines 7-8);
- claim 30 – “improve imbalance of an neuro-endocrinological system” (lines 7-8),
- claim 31 – “improving imbalance of the endocrinological system” (lines 1-3),
- claim 32 – “improving imbalance of the neuro-endocrinological system” (lines 1-3) and “alter the neuro-endocrinological system” (lines 9-10),
- claim 33 – “treating imbalance of the endocrinological system ” (lines 1-2).

Applicant is required to cancel the new matter in the reply to this Office Action.

8. The status of the cases on page 1 of the specification continues to need to be updated.

*Information Disclosure Statement*

9. The information disclosure statement filed 6/12/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The information disclosure sheet has been placed in the application file with the

ten foreign references (BR-CA) lined through; the foreign references (BR-CA) have not been considered.

10. The information disclosure statement filed 6/12/064 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance of fourteen non-patent literature references (CB, CC, DH, DI, and EH-DQ), as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The information disclosure sheet has been placed in the application file with the fourteen noted non- patent literature references (CB, CC, DH, DI, and EH-DQ) lined through; the fourteen non- patent literature references (CB, CC, DH, DI, and EH-DQ) have not been considered.

***Other Prior Art Cited***

11. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. US 5203326 to Collins teaches treatment of abnormal cardiac rhythms with electrical stimulation of the heart and the nerves (abstract).

***Statutory Basis***

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

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8-18-06

  
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